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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,865	02/02/2001	Carl G. Hellerqvist	49530/252687 (0100)	7056

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EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	PAPER NUMBER
1643	
MAIL DATE	DELIVERY MODE
12/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/776,865	HELLERQVIST, CARL G.	
	Examiner	Art Unit	
	Stephen L. Rawlings	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,15,16,59-61,64,89,91,93 and 94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 15, 16, 59-61, 64, 89, 91, 93, and 94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 February 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20080904*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed September 3, 2008, is acknowledged and has been entered. Claims 31, 33-38, 40-42, 45, 46, 72-88, 90, and 92 have been canceled. Claims 1, 4, 5, 8-10, 15, 59, and 60 have been amended. Claims 93 and 94 have been added.

2. Claims 1, 4, 5, 8-10, 15, 16, 59-71, 89, 91, 93, and 94 are pending in the application. Claims 5, 8-10, 62, 63, and 65-71 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species of invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 29, 2007.

3. Claims 1, 4, 15, 16, 59-61, 64, 89, 91, 93, and 94 are currently under prosecution.

Information Disclosure Statement

4. The information disclosure filed September 4, 2008, has been considered. An initialed copy is enclosed.

Terminal Disclaimer

5. The terminal disclaimer filed on September 3, 2008, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,803,448 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Grounds of Objection and Rejection Withdrawn

6. Unless specifically reiterated below, Applicant's amendment and/or arguments have obviated or rendered moot the grounds of objection and rejection set forth in the previous Office action mailed March 3, 2008.

Priority

7. Applicant's claim under 35 U.S.C. §§ 119(e) and/or 120, 121, or 365(c) for benefit of the earlier filing date of Provisional Application No. 60/179,870, filed February 2, 2000, is acknowledged.

However, claims 1, 4, 15, 16, 59-61, 64, 89, 91, 93, and 94 do not properly benefit under §§ 119 and/or 120 by the earlier filing dates of the priority documents claimed, since those claims are rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description and a sufficiently enabling disclosure.

To receive benefit of the earlier filing date under §§ 119 and/or 120, the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). See M.P.E.P. § 201.11.

Accordingly, the effective filing date of claims 1, 4, 15, 16, 59-61, 64, 89, 91, 93, and 94 is deemed the filing date of the instant application, namely February 2, 2001.

Grounds of Objection

Claim Objections

8. Claims 59-61, 89, 91, and 94 are objected to as being specifically directed in the alternative to the subject matter of non-elected species of invention.

Grounds of Rejection

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 4, 15, 16, 59-61, 64, 89, 91, 93, and 94 are rejected under 35 U.S.C. 112, first paragraph, because the specification, **while being enabling for making**

a composition comprising a peptide consisting of amino acids 8-28 of the amino acid sequence of SEQ ID NO: 2 and a composition comprising a polypeptide comprising of the amino acid sequence of SEQ ID NO: 2 (see proposed claim amendments that follow for more detail), **while being enabling for using** a process for eliciting an immune response in a mammal, said process comprising administering to said mammal any of said compositions (see proposed claim amendments that follow for more detail), **while being enabling for using** a process for attenuating the progression of the growth in size of melanomas or Lewis lung tumors in mice, said process comprising administering to said mice a composition comprising a peptide consisting of amino acids 8-28 of the amino acid sequence of SEQ ID NO: 2, a peptide consisting of amino acids 112-125 of the amino acid sequence of SEQ ID NO: 2, and a peptide consisting of amino acids 49-63 of the amino acid sequence of SEQ ID NO: 2, **and while being enabling for making and/or using** any subject matter encompassed by the claims, which is taught in the prior art, **does not reasonably provide enablement for making and/or using** the claimed subject matter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to making and/or using the invention commensurate in scope with these claims.

Beginning at page 8 of the response filed September 3, 2008, Applicant has traversed the propriety of maintaining such a ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for reasons that have been made of record.

In short, it is submitted that the amount of guidance, direction and exemplification set forth in this application is not reasonably commensurate with claims of such breadth, so as to enable the production and/or use of the claimed subject matter without undue and/or unreasonable experimentation.

Accordingly, Applicant has been reminded that reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

Thus, although Applicant's arguments and the merit of declarations by the inventor have been carefully considered, upon equally careful consideration of the factors used to determine whether undue experimentation is required, in accordance with the

Federal Circuit decision of *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), it has been determined that the amount of guidance, direction, and exemplification disclosed in the specification, as filed, would not have been sufficient to have enabled the skilled artisan to make and/or use the claimed invention at the time the application was filed without undue and/or unreasonable experimentation.

Nonetheless, as discussed during the interviews of June 27, 2008[1], and October 15, 2008[2], held with Applicant's representative, Dr. Polovnikova, it is submitted that amending of the claims as follows would obviate outstanding issues related to insufficiency of the specification to provide a reasonably enabling disclosure, as well as an adequate written description.

However, as also noted during the interview of October 15, 2008, even if Applicant was to have agreed to amend the claims as suggested, the claims would remain unpatentable over the prior art.

In particular, it was noted that there would be remaining issues under 102(e) in view of the disclosures of U.S. Patent No. 6803448 and U.S. Patent Application Publication No. 20050002931, as well as that of the as yet unpublished application No. 12/142,060.

Dr. Polonikova indicated that Applicant plans to provide a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or otherwise an appropriate showing under 37 CFR 1.131 to obviate these remaining issues, once a determination of inventorship has been made.

The following amendment to the claims was proposed, which again if entered would not place this application in condition for allowance, but would obviate substantive issues under 112/first paragraph, leaving only issues under 102 and/103:

Claims 1-94. (Canceled)

[1] See the Interview Summary mailed July 3, 2008.

Claim 95. (New) A method of inducing an immune response in a mammal to the HP59 Group B β-hemolytic Streptococci toxin receptor of SEQ ID NO: 2, said method comprising administering to the mammal a composition comprising an effective amount of the polypeptide of SEQ ID NO: 2 or at least one immunogenic fragment thereof to induce an immune response in the mammal to the HP59 Group B β-hemolytic Streptococci toxin receptor, wherein said immune response comprises the production of antibodies that recognize the HP59 Group B β-hemolytic Streptococci toxin receptor and/or the stimulation of T cells that will recognize the HP59 Group B β-hemolytic Streptococci toxin receptor and elicit a cytotoxic response toward cells expressing the HP59 Group B β-hemolytic Streptococci toxin receptor.

Claim 96. (New) The method of claim 95, wherein said composition comprises the polypeptide of SEQ ID NO: 2.

Claim 97. (New) The method of claim 95, wherein said composition comprises an immunogenic fragment of the polypeptide of SEQ ID NO: 2.

Claim 98. (New) The method of claim 97, wherein said immunogenic fragment is a peptide selected from the group consisting of Hab1, Hab2, Hab3, and Hab4, wherein said Hab1 consists of the amino acid sequence of amino acids 49-63 of SEQ ID NO: 2, Hab2 consists of the amino acid sequence of amino acids 112-125 of SEQ ID NO: 2, Hab3 consists of the amino acid sequence of amino acids 8-28 of SEQ ID NO: 2, and Hab4 consists of the amino acid sequence of amino acids 49-76 of SEQ ID NO: 2.

Claim 99. (New) The method of claim 95, wherein said composition further comprises a pharmaceutically acceptable excipient.

Claim 100. (New) The method of claim 95, wherein said composition further comprises an adjuvant.

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[2] See the Interview Summary mailed October 17, 2008.

Claim 101. (New) The method of claim 97, wherein said immunogenic fragment is conjugated to a protein carrier.

Claim 102. (New) The method of claim 101, wherein said protein carrier is selected from the group consisting of keyhole limpet hemocyanin, bovine serum albumin, ovalbumin, human serum albumin, human gamma globulin, chicken immunoglobulin G, bovine gamma globulin, and tetanus toxoid.

Claim 103. (New) The method of claim 95, wherein said composition is administered to the mammal orally, rectally, parenterally, subcutaneously, intravenously, intramuscularly, intraperitoneally, or intranasopharangeally.

Claim 104. (New) The method of claim 95, wherein said mammal has melanoma.

Claim 105. (New) The method of claim 95, wherein said mammal has lung cancer.

Claim 106. (New) A method of inducing an immune response in a mammal to the HP59 Group B β-hemolytic Streptococci toxin receptor of SEQ ID NO: 2, said method comprising administering to the mammal a composition comprising an effective amount of a polypeptide comprising an amino acid sequence that is at least 90% identical to the amino acid sequence of SEQ ID NO: 2 to induce an immune response in the mammal to the HP59 Group B β-hemolytic Streptococci toxin receptor, wherein said immune response comprises the production of antibodies that recognize the HP59 Group B β-hemolytic Streptococci toxin receptor and/or the stimulation of T cells that will recognize the HP59 Group B β-hemolytic Streptococci toxin receptor and elicit a cytotoxic response toward cells expressing the HP59 Group B β-hemolytic Streptococci toxin receptor.

Claim 107. (New) A method of inducing an immune response in a mammal to the SP55 Group B β-hemolytic Streptococci toxin receptor of SEQ ID NO: 4, said method comprising administering to the mammal a composition comprising an effective amount of the polypeptide of SEQ ID NO: 4 or at least one immunogenic fragment thereof to induce an immune response in the mammal to the SP55 Group B β-hemolytic Streptococci toxin receptor, wherein said immune response comprises the production of antibodies that recognize the SP55 Group B β-hemolytic Streptococci toxin receptor and/or the stimulation of T cells that will recognize the SP55 Group B β-hemolytic Streptococci toxin receptor and elicit a cytotoxic response toward cells expressing the SP55 Group B β-hemolytic Streptococci toxin receptor.

Claim 108. (New) A method of inducing an immune response in a mammal to the SP55 Group B β-hemolytic Streptococci toxin receptor of SEQ ID NO: 4, said method comprising administering to the mammal a composition comprising an effective amount of a polypeptide comprising an amino acid sequence that is at least 90% identical to the amino acid sequence of SEQ ID NO: 4 to induce an immune response in the mammal to the SP55 Group B β-hemolytic Streptococci toxin receptor, wherein said immune response comprises the production of antibodies that recognize the SP55 Group B β-hemolytic Streptococci toxin receptor and/or the stimulation of T cells that will recognize the SP55 Group B β-hemolytic Streptococci toxin receptor and elicit a cytotoxic response toward cells expressing the SP55 Group B β-hemolytic Streptococci toxin receptor.

11. The rejection of claims 1, 4, 15, 16, 59-61, 64, 89, 91, 93, and 94 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Beginning at page 8 of the response filed September 3, 2008, Applicant has traversed the propriety of maintaining such a ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for reasons that have been made of record.

In short, for reasons already of record, it is submitted that the subject matter encompassed by the claims is not adequately described in the specification with the requisite clarity and particularity to satisfy the written description requirement, so as to reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

Nonetheless, as discussed above, it is submitted that amending of the claims as has been suggested would obviate outstanding issues related to insufficiency of the disclosure to provide adequate written description of the claimed invention.

However, as also noted discussed above, even if Applicant was to have agreed to amend the claims as suggested, the claims would remain unpatentable over the prior art; but again Dr. Polonikova indicated that Applicant plans to provide a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or otherwise an appropriate showing under 37 CFR 1.131 to obviate these remaining issues, once a determination of inventorship has been made.

Conclusion

12. No claim is allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

slr
December 7, 2008